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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,177	12/06/2006	Martin Parratt	010180.00040	1861
22907 7590 05/13/2008 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051			EXAMINER RAE, CHARLESWORTH E	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 05/13/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,177	<b>Applicant(s)</b> PARRATT ET AL.	
	<b>Examiner</b> CHARLESWORTH RAE	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 10-12, 14, 15, 18-20, 23, 25-28 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 13, 16-17, 21-22, 24, 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

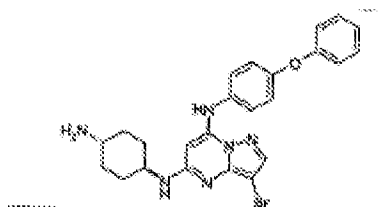
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/6/06</u>                                                   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicant's response with traverse, received 2/20/08, to the restriction/election requirements, mailed 1/24/08, electing invention I (claims 1-33, and 39), and compound 181 as shown below as the compound species (see specification, page 68), is acknowledged (see specification, page 68):



Applicant's preliminary claim amendment, filed 2/20/08, is also acknowledged.

Applicant's statement that claims 1-5, 9, 13, 16, 17, 21, 22, 24, and 29-33 read on the elected compound species is acknowledged and made of record.

### Status of the Claims

Claims 1-34, and 36-40 are pending in this application.

Claims 6-8, 10-12, 14-15, 18-20, 23, 25-28, and 34-40 are withdrawn for being directed to non-elected subject matter.

Claims 1-5, 9, 13, 16-17, 21-22, 24, and 29-33 are presented for examination.

### Restriction/Election

Applicant's response to the restriction/election requirements is considered to be without traverse because applicant has failed to specifically point out any error in the requirements.

### **Foreign Priority**

Receipt of applicant's certified copies of the four (4) foreign priority documents, received 9/29/05, are acknowledged.

It is noted that except for the priority document 0325854.8, the above referenced priority documents are not found to provide proper support for applicant's elected species. However, applicant is invited to point to the examiner the specific page and line numbers in the other priority documents where support may be found for said elected compound species.

For examination purposes, the effective filing date for the elected subject matter is considered to be November 5, 2003 (i.e. filing date of priority document 0325854.8).

### ***Claim Rejections – 35 USC 112 – First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 9, 13, 16-17, 21-22, 24, and 29-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for compounds capable of reducing the activity of certain kinases, does not reasonably provide enablement for any and all compounds having the general formula recited in instant claim 1 for inhibiting the activity of any and all kinases. This is a scope of enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if its is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *PPG v Guardian*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman* 230 USPQ 546 (BdApls 1986) at 547 the court cited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art.

The invention in general relates to compounds that exhibit inhibitory kinase activity.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. It is noted that the chemical and medical arts are generally unpredictable, requiring each embodiment to be individually assessed for chemical, pharmacologic, pharmaceutical, and clinical efficacy. The more unpredictable an area, the more specific enablement is necessary in order to satisfy the statute. (see *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)).

Porter et al. (Porter et al. Tyrosine kinase receptor-activated signal transduction pathways which lead to oncogenesis. *Oncogene*. 1998;17:1343-52). Porter et al. teach that oncogenesis is a complicated process involving signal transduction pathways that mediate many different physiological events (abstract). Typically, oncogenes cause unregulated cell growth and this phenotype has been attributed to the growth-stimulating activity of oncogenes such as ras and src (abstract). In recent years, much research effort has focused on proteins that function downstream of Ras, leading to the

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identification of the Ras/Raf/MAPK pathway, because activation of this pathway leads to cellular proliferation. Activated receptor tyrosine kinases (RTKs) also utilize this pathway to mediate their growth-stimulating effects. However, RTKs activate many other signaling proteins that are not involved in the cellular proliferation process, which are also believed to contribute to the oncogenic process (abstract). In fact, RTKs and many of the proteins involved in RTK-dependent signal transduction can also function as oncogenes (abstract). For example, the catalytic subunit of phosphoinositide 3-kinase (P13-K) was recently identified as an oncogenic protein (abstract). The scope of pathways that are activated by oncogenic RTKs is expanding(abstract). Thus, not only do RTKs activate Ras-dependent pathways that drive proliferation, RTKs activate P13-K-dependent pathways which also contribute to the oncogenic mechanism (abstract). P13-K can initiate changes in gene transcription, cytoskeletal changes through beta-catenin, changes in cell motility through the tumor suppressor, adenomatous polyposis coli (APC), and phosphorylation of BAD, a protein involved in apoptotic and antiapoptotic signaling (abstract). There is also cross-talk between RTKs and the oncostatin cytokine receptor which may positively and negatively influence oncogenesis (abstract).

## 2. The breadth of the claims

The instant claims are relatively broad in scope. The formula recited in claim 1 encompasses a multiplicity of different chemical compounds, which would reasonably exhibit different pharmacologic and toxicity profiles, as well as different or varying degrees of inhibitory activity against the same or different kinases. Because the

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therapeutic response to be achieved would necessarily vary depending upon the affinity of the specific compound for a given kinase receptor, the level of predictably in practicing the claimed invention commensurate with the full scope of the claims would be greatly diminished.

3. The amount of direction or guidance provided and the presence or absence of working examples

Based on the instant disclosure, the applicant at best has provided specific direction or guidance only for a general method of making the disclosed compounds. No reasonably specific guidance is provided concerning useful protocols for determining the activity of the compounds encompassed by the instant claims without conducting extensive experimentation.

4. The quantity of experimentation necessary

In view of the uncertainty and unpredictability of the art as evidenced by the discussion of the prior art, it is reasonable to surmise that this level of uncertainty in the art would require one skilled in the art to conduct more than routine experimentation in order to practice the claimed invention commensurate with the scope of the claims.

For the reasons stated above, claims 1-5, 9, 13, 16-17, 21-22, 24, and 29-33 are rejected under 35 USC 112, first paragraph, for lack of scope enablement because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims.



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***Claim rejections – 35 USC 112 – Second Paragraph***

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-5, 9, 13, 16-17, 21-22, 24, and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the confusing term “Q represents a radical formula (  $\text{alk1}$ )p-(X)r-(Alk2)s-Z wherein in any compatible combination Z is hydrogen or an optionally substituted carbocyclic or heterocyclic ring”, which renders the claimed subject matter indefinite because it is not clear what specific combinations are compatible. In particular, the term “wherein in any compatible combination,” does not reasonably relate back to any specific claim limitation. Thus, the term “Q represents a radical formula (  $\text{alk1}$ )p-(X)r-(Alk2)s-Z wherein in any compatible combination ...” is found to be unclear.

Claims 2-5, 9, 13, 16-17, 21-22, 24, and 29-33 are rejected for the same reason as these claims fail to correct the deficiency of the claim from which they depend.

***Claim rejections – 35 USC 103(a)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

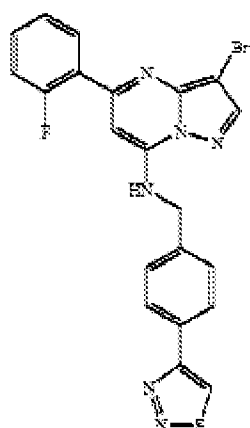
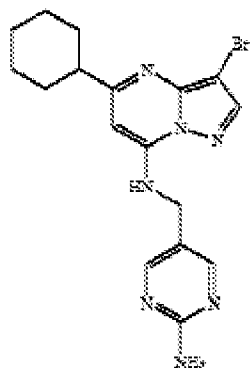
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 9, 13, 16-17, 21-22, 24, and 29-33 are rejected under 103(a) as being unpatentable over Guzi et al. (US Patent 7,119,200), in view of Wilde et al. (US Patent 7,291,603) and Himmelsback et al. (US Patent 5,821,240).

The term "divalent alkylene C1-C6 alkylene radical" as recited in claim 1, given its broadest reasonable possible interpretation, is construed to be a "divalent saturated aliphatic radical (as ethylene) derived from an alkene by opening of the double bond;" this meaning is considered by the examiner to preclude a phenyl ring as evidenced by the teaching of Webster's Third New International Dictionary, 1963, page 54, and Brown et al. (US Patent Application Pub. No. 2005/026133 A1; para 0037).

Guzi et al. (US Patent 7,119,200) teach pyrazolo(1,5-a) pyrimidine cyclin dependent kinase inhibitor compounds useful for treating diseases associated with CDKJs, including the below compounds (col. 1, line 30 to col. 6, line 19; col. 18, lines 25-41; and col. 24, lines 47-65):

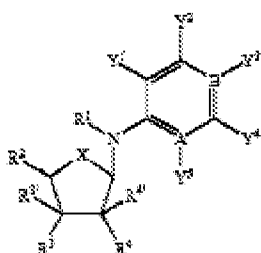


As can be seen from the above examples, applicant's elected compound have a similar core structure as the compounds taught Guzi et al. Also, substitution of a cylohexyl with a phenyl group at the R1 position of the above compounds taught by Guzi et al. does not alter the therapeutic properties of the compounds taught by Guzi et al. (col. 1, line 30 to col. 6, line 19; col. 18, lines 25-41; and col. 24, lines 47-65; see also Formula 1 recited in instant claim 1) ). Also, as can be seen from the second structure delineated above, Guzi et al. teach a phenyl group as the equivalent of the A ring as recited in

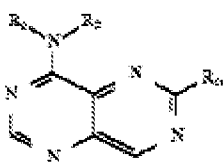
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claim 1. However, the compounds taught by Guzi et al. differ from the instant claimed compounds with respect to 1) the cyclohexyl group at the R1 position of the instant elected compound is substituted by an amino group, while the cyclohexyl group taught by Guzi et al. is unsubstituted and 2) the phenyl A ring of applicant's elected compound species is directly connected to the nitrogen atom and is further substituted by a phenoxy substituent, while Guiz et al. disclose an intervening methyl group connecting the nitrogen to the equivalent phenyl A ring, which is further substituted by a 5-membered heterocyclic ring.

Wilde et al. (US Patent 7,291,603) teach that small molecule therapeutics or prophylactics that suppress premature translation termination by mediating the misreading of the nonsense codon would be useful for the treatment of a number of diseases and that the discovery of small molecule drugs, particularly orally bioavailable drugs, can lead to the introduction of a broad spectrum of selective therapeutics or prophylactics to the public which can be used against disease caused by nonsense mutations is just beginning (col. 3, lines 15-23). In particular, Wilde et al. exemplify compounds having the below formula for useful for treating a non-limited number of conditions, including cancers, autoimmune diseases, cardiovascular diseases, diabetes, inflammatory diseases, tuberous sclerosis, pulmonary diseases, blood diseases, collagen diseases, neurodegenerative diseases, and central nervous system diseases(col. 3, line 46 to col.6, line 13):



Himmelsback et al. is added to show the general knowledge in the art regarding phenylphenoxy substituent on a pyrimidine ring. Himmelsback et al. (US Patent 5,821,240) teach tyrosine kinase inhibitors useful for treating oncoses having the below pyrimido[5,4-d]dipyrimidine general formula (col. 1, line 5, to col. 5, line 20; see especially reference claim 1):



their tautomers, their stereoisomers and their salts, in particular their physiologically tolerated salts with inorganic or organic acids or bases, which have valuable pharmacological properties, in particular an inhibitory effect on signal transduction mediated by tyrosine kinases, their use for the treatment of disorders, in particular of oncoses, and their preparation.

Himmelsback et al. exemplify compounds wherein Ra is hydrogen (see especially, col. 58, line 12), Rb is 4-phenoxyphenyl (see especially col. 58, line 19), and Rc is a cyclohexyl group substituted in position 4 with an amino group (see especially col. 60, lines 4-5).

Based on the teaching of Wilde et al. that small molecule therapeutics or prophylactics that suppress premature translation termination by mediating the misreading of the nonsense codon would be useful for the treatment of a number of

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diseases and that the discovery of small molecule drugs, particularly orally bioavailable drugs (col. 3, lines 15-23), someone of skill in the art would have been motivated to combine the teachings of the above cited references to create the instant claimed compound.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed compound with reasonable expectation of success because an ordinary artisan would have reasonable expectation that any species of the general core structure shared between the claimed compound and the cited prior art would have similar properties as the genus as a whole, and thus, the same utility.

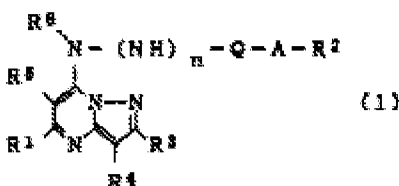
#### **Relevant Art of Record**

The below cited art made of record and relied upon are considered pertinent to applicant's invention or presented as evidentiary references (i.e. Webster's dictionary and Brown et al.).

Brown et al. (US Patent Application Pub. No. 2005/026133 A1) teach that the term "alkylene" refers to a straight or branched chain unsaturated aliphatic hydrocarbon radical that may be optionally substituted, with multiple degrees of substitution being allowed. Examples of "alkylene" include, but are not limited to methylene, ethylene, n-propylene, n-butylene, and the like (para. 0037).

The term "alkylene" is defined as a "divalent saturated aliphatic radical (as ethylene) derived from an alkene by opening of the double bond." See Webster's Third New International Dictionary, 1963, page 54.

Sato et al. (JP 2000-239345; abstract only) teach pyrazolo(1,5-a)pyrimidine angiogenesis adjusting agents with the below general structure:



wherein R1 = H, lower alkyl optionally substituted with thienyl, lower alkoxy, lower alkylthio, oxo or hydroxyl, cycloalkyl, thienyl, furyl, lower alkenyl, or phenyl optionally substituted with 1-3 substituents selected from lower alkyl, lower alkoxy, phenylthio and halogen; R2 = naphthyl, cycloalkyl, furyl, thenyl, pyridyl optionally substituted with halogen, phenoxy optionally substitute with halogen, or phenyl optionally substituted with 1-3 substituents selected from lower alkyl, lower alkoxy, halogen, nitro, halogen substituting lower alkyl, halogen substituting lower alkoxy, (lower alkoxy)carbonyl, hydroxyl, phenyl(lower alkoxy), amino, cyano, (lower alkanoyl)oxy, phenyl and di(lower alkoxy)phosphoryl(lower alkyl); R3 = H, phenyl or lower alkyl; R4 = H, lower alkyl, lower alkoxycarbonyl, phenyl(lower alkyl), phenyl optionally substituted with phenylthio, or halogen; R5 = H or lower alkyl; R6 = H, lower alkyl, phenyl(lower alkyl), or benzoyl having 1-3 substituents selected from lower alkoxy, halogen substituting lower alkyl and halogen; R1 and R5 may bind to each other to form lower alkylene; Q = carbonyl or sulfonyl; A = single bond, lower alkylene or lower alkenylene; and n = 0 or 1.

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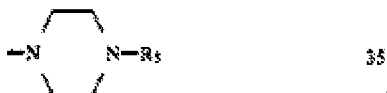
Tomcufcik et al. (US Patent 4,576,943) teach pyrazolo-[1,5a]-pyrimidine compounds that are useful as hypotensive and/or anxiolytic agents having the below formula:



wherein  $R_1$  is hydrogen, methyl or trifluoromethyl;  $R_2$  is cyano, carbamoyl or a moiety of the formula:



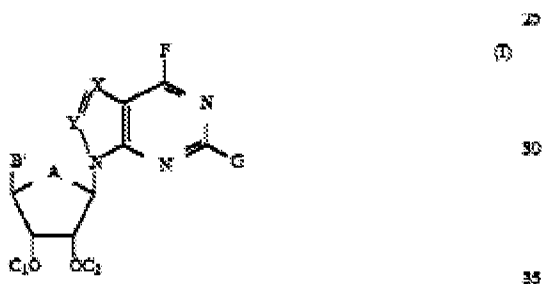
$R_3$  is phenyl, 3-chlorophenyl, 4-chlorophenyl, 3-(trifluoromethyl)phenyl, 3-pyridyl or 4-pyridyl; and  $R_4$  is 1-piperidino, 4-benzyl-1-piperidino, 4-morpholino, 4-thiomorpholino or a moiety of the formula:



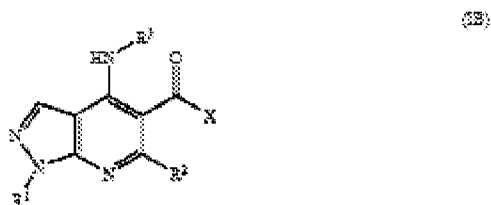
wherein  $R_5$  is methyl, phenyl, 2-pyridyl, 2-furanyl, methyl, 3-phenyl-2-propenyl, benzyl, 3-chlorobenzyl, 4-chlorobenzyl, 3,4-dichlorobenzyl, 2,6-dichlorobenzyl, 3-methoxybenzyl, 4-methoxybenzyl,  $\beta$ -hydroxyethyl, 2-phenoxyethyl, 3-phenoxypropyl or 4-phenoxybutyl; and the pharmacologically acceptable acid-addition salts thereof.

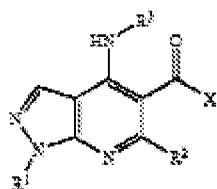
Firestein et al (US Patent 5,646,128) teach adenosine kinase inhibitors and methods of preparing adenosine kinase inhibitors, specifically to purine, pyrrolo[2,3-d]pyrimidine and pyrazolo[3,4-d]pyrimidine nucleoside analogs having activity as adenosine kinase inhibitors for use in the treatment of inflammation, sepsis, septic shock, burns and diseases which can be regulated by increasing the local concentration of adenosine, wherein said compounds have the below general formula (col. 1, line 19 to col 4, line 22, and col. 7, line 21 to col. 8, line 10):





Allen et al. (US Patent Application Pub. No. 2006/0089375 A1) pyrazolopyridine compounds, processes for their preparation, intermediates usable in these processes, and pharmaceutical compositions containing the compounds. The invention also relates to the use of the pyrazolopyridine compounds in therapy, for example as inhibitors of phosphodiesterases and/or for the treatment and/or prophylaxis of inflammatory and/or allergic diseases such as chronic obstructive pulmonary disease (COPD), asthma, rheumatoid arthritis or allergic rhinitis (abstract). In particular, Allen et al. disclose compounds having the below general formula (paras. 0408-0440):





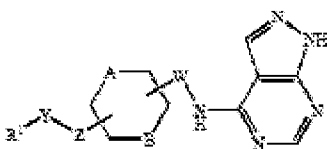
(32)

wherein:

[0409] R<sup>1</sup> is C<sub>1-6</sub>alkyl, C<sub>1-6</sub>fluoroalkyl, —CH<sub>2</sub>CH<sub>2</sub>OH or —CH<sub>2</sub>CH<sub>2</sub>CO<sub>2</sub>C<sub>1-6</sub>alkyl;

[0410] R<sup>2</sup> is a hydrogen atom (H), methyl or C<sub>1</sub>fluoroalkyl;

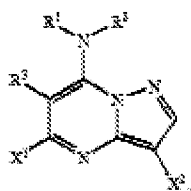
Thompson et al. (US Patent Application Pub. No. 20070037829) teach compounds that are NMDA/NR2B antagonists useful for the treatment of neurological conditions such as pain, Parkinson's disease, Alzheimer's disease, epilepsy, depression, anxiety, ischemic brain injury including stroke, and other conditions, having the below general formula (paras. 00005-0022):



(33)

Gebauer et al. (US Patent Application Pub. No. 2006/0089499 A1) teach pyrazolopyrimidines with superior insecticidal and nematicidal action, as well as methods of preparing said compounds, having the below general formula (paras 001-0032; see also reference claims 13-14):

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in which

$R^1$  represents amino or hydroxyl; or represents optionally substituted alkyl, alkenyl, alkynyl, cycloalkyl, alkoxy, alkenyloxy, alkynyloxy, cycloalkyloxy, alkylamino, dialkylamino, alkylamino, alkynylamino, cycloalkylamino, N-cycloalkyl-N-alkylamino, alkylideneamino, or heterocyclyl,

$R^2$  represents hydrogen; or represents optionally substituted alkyl, alkenyl, alkynyl, or cycloalkyl, or

$R^1$  and  $R^2$  together with the nitrogen atom to which they are attached form an optionally substituted heterocyclic ring,

$R^3$  represents optionally substituted aryl,

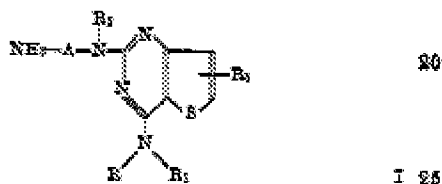
$X^1$  represents hydrogen or halogen, and

$X^2$  represents halogen, cyano, nitro, alkyl, haloalkyl, cycloalkyl, formyl, thiocarbonyl, alkoxy carbonyl, alkyl carbonyl, hydroximinomethyl, or alkoximinomethyl,

with the proviso that when  $R^1$  represents amino, the pyrazolopyrimidine of formula (3) is optionally in the form of an acid addition salt.

Woitun et al. (US Patent 3,838,121) teach 2-(aminoalkylamino)-thien [3,2-d]pyrimidines having the below general formula (see abstract):

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wherein R and R<sub>1</sub> may be the same or different and are selected from the group consisting of hydrogen and straight and branched alkyl of 1 to 6 carbon atoms and taken together with the nitrogen atom to which they are attached form a saturated 5 to 7 member heterocyclic ring which can optionally contain an oxygen or nitrogen heteroatom and may be substituted with alkyl of 1 to 6 carbon atoms or hydroxyl, R<sub>2</sub> is selected from the group consisting of hydrogen and straight and branched alkyl of 1 to 6 carbon atoms, R<sub>3</sub> is selected from the group consisting of methyl in the 6- or 7-position and hydrogen and A is a straight or branched alkylene of 2 to 10 carbon atoms and their non-toxic, pharmaceutically acceptable acid addition salts which possess cardiovascular and sedative activity and inhibit platelet aggregation, and processes for their preparation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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6 May 2008

Examiner /C.R./

/Brian-Yong S Kwon/

Primary Examiner, Art Unit 1614